

REMARKS/ARGUMENTS

In the Office Action of July 22, 2004, the Examiner allowed claims 2, 5, and 6. The Examiner objected to Figures 5-7 as being unclear. The Examiner rejected claim 26 under 35 U.S.C. §112, first paragraph as containing new matter. The Examiner rejected claims 1, 3, and 26 under 35 U.S.C. §112, second paragraph as being indefinite. Finally, the Examiner rejected claim 4 under 35 U.S.C. §102(b) as being anticipated by Kuroda *et al.*, (1993, JP05-281230, hereinafter "Kuroda"). Claims 1-3, 5-6, and 26 were noted to be free of the prior art and thus, claims 1 and 3 were noted to be allowable if rewritten to overcome the above-noted §112 rejections.

By this paper, claims 1, 3, and 4 have been amended to address 35 U.S.C. §112 and 35 U.S.C. §102 rejections listed above. Replacement sheets have been provided to overcome the Examiner's objection to Figures 5-7. Thus, claims 1-6 and 26 are presented herewith for reconsideration.

REMARKS

Claim Rejections – 35 U.S.C. §112, First Paragraph

The Examiner first rejected claim 26 under 35 U.S.C. §112, first paragraph as containing subject matter not described in the original specification "in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action, para. 3. Specifically, the Examiner believes that the limitation of "the solid support comprises a magnetically responsive bead" of claim 26 is not supported by the original specification.

The Applicants respectfully traverse this rejection and assert that the specification fully discloses the use of magnetic beads as a solid support. For examples of this, *see, e.g.*, p. 41, lines 1-18; p. 44, lines 2-7; p. 47, lines 15-22; and p. 51, lines 20-32 of the published application. In one example from page 41, "anti-digoxigenin-coated magnetic beads" were used in an example of a separation method of the invention. The other references provided above also discuss the

use of magnetic beads as a solid support in the methods of the invention. The Applicants believe that these references provide adequate support for claim 26 under section 112, first paragraph, and thus Applicants respectively request the withdrawal of this rejection.

Claim Rejections – 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1, 3, and 26 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, these claims were rejected as not including antecedent basis support for the term “the first mixture” used in part (c) of claims 1 and 3, and claim 26, dependent from claim 1. Claims 1 and 3 are amended above to recite “the mixture” to provide proper antecedent support for this limitation.

Claim 3 was next rejected under 35 U.S.C. §112, second paragraph as being indefinite for having a preamble which recites a method of diagnosing a disease or disorder, but including method steps appearing to result in detecting a nucleic acid having two sequence types. Claim 3 has been amended to explain that detection of the presence or increased quantity of a nucleic acid containing both the first nucleotide sequence type and the second nucleotide sequence type supports a diagnosis of the presence of the disease or disorder, and that an absence or reduced quantity of a nucleic acid containing both the first nucleotide sequence type and the second nucleotide sequence type supports a diagnosis of the absence of the disease or disorder. This amendment is supported by the specification, including a discussion at page 7, line 28-page 8, line 11. As a result, the Applicants respectfully request withdrawal of this rejection.

Claim Rejections – 35 U.S.C. §102(b)

Claim 4 was rejected under 35 U.S.C. §102(b) as being anticipated by Kuroda. In order for a reference to anticipate a claim under 35 U.S.C. §102(b), “each and every element as set forth in the claim [must be] found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), cited in MPEP §2131. The MPEP further clarifies that “[t]he identical invention must be shown in as complete detail as is contained in the claim.” MPEP §2131, quoting *Richardson v. Suzuki*

Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Applicants submit that as amended above, claim 4 is not anticipated by Kuroda, and thus should be allowed.

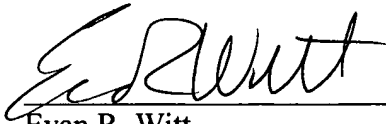
As amended herein, claim 4 teaches a kit for separating a nucleic acid containing both a first nucleotide sequence type and a second nucleotide sequence type. As presented in claim 4, the kit includes a first probe-bead complex comprising a first hybridization probe and a magnetically responsive bead; a second probe-bead complex comprising a second hybridization probe and a magnetically non-responsive bead with a feature distinguishable from the first bead; and instructions for using the first probe-bead complex and the second probe-bead complex to separate a nucleic acid containing a first nucleotide sequence type and a second nucleotide sequence type from a sample. Those instructions are claimed to comprise “the steps of mixing the first and second probe-bead complexes with the sample to form a mixture, separating the first probe-bead complex and nucleic acids hybridized thereto from the mixture using a magnetic force to obtain a first nucleotide sequence fraction, and separating the second probe-bead complex and nucleic acids hybridized thereto from the first nucleotide sequence fraction according to the properties of the distinguishable feature of the second bead to obtain a nucleotide fraction of sequences containing nucleic acids containing both the first and second nucleotide sequence types.” Claim 4, *supra*.

In the Office Action of July 22, 2004, the Examiner noted that Kuroda fails to anticipate claims 1-3, 5-6, and 26 since “Kuroda et al. do not teach or suggest a second separation step, however, wherein the second probe-bead complex and nucleic acids hybridized thereto are separated from the fraction comprising the first nucleotide sequence type according to the properties of the distinguishable feature of the second bead.” Office Action, p. 5. As repeated above, claim 4 has been amended to include a limitation requiring a set of instructions including first and second separation steps. As stated by the Examiner, methods having first and second separation steps as taught in the instant application are allowable over Kuroda. The Applicants submit that claim 4, now incorporating instructions to these novel separation steps, is allowable.

Applicants respectfully request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Appl. No. 10/089,560
Amdt. dated September 10, 2004
Reply to Office Action of July 22, 2004.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. R. Witt", written over a horizontal line.

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Amendments to the Drawings:

The attached two sheets of drawings include clearer copies of Figures 5-8, intended to replace the originally-filed Figures 5-7 which were objected to as being unclear. Thus, the attached two sheets are intended to replace the original sheets, including Figures 5-8. Replacement Figures 5-7 are copies of the figures originally filed in PCT/US00/27883.

Attachment: Two Replacement Sheets, sheet 8/16 and sheet 9/16.